Operating Instructions

ASTODIA

Transilluminator

FUTUREMED®

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Stuttgart, Germany

Part Num. DIA100 - Rev. 2 - July, 2009

To be filled in by the user:

Serial number _____

Stock number _____

Device location _____

Date of commissioning _____

Contact Information:

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INSTRUCTIONS FOR MEDICAL USE
<according to the Medical Safety/EMC standard IEC/EN 60601-1-2>
Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.
Portable and mobile RF communications equipment can affect medical electrical equipment.

CE

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1. Introduction

The Diaphanoscope ASTODIA serves for searching blood vessels and helps identify structures filled with air or fluid deep under the skin surface.
Known factors of influence and application limits of this method are the luminous intensity, the patient's size and the ambient light intensity.
This is the reason why the ASTODIA is especially suitable for patients in the field of paediatrics and preferably for premature babies and neonates. This device can help indicate vessels in limbs for puncture and it provides for fast detection of a pneumothorax or a hydrocele.

Indications and Intended Use

ASTODIA is only allowed to be used by professional medical personnel.
It serves for the translumination of the biological tissue, to visualize its structures; e.g. in the overextentioned, neonatal wrist joint of the dorsopalmar, to punctuate the radial and ulnar arteries while they are visible.
Two high-performance light-emitting diodes of different wave length (yellow and red) are used for a wide range of applications. The thermal load for the transilluminated tissue is minimized and regulated by an electronic control unit.
ASTODIA is a battery-powered transilluminator with rechargeable batteries.

Contraindications

Contraindications for the transillumination of tissue using visible light are not known for the intended use.

It is absolutely required to read the operating instructions before using this product.

Warnings

1 In case ASTODIA starts directly after switch on in the highest light level and a change of the highest level is not possible - then do not use ASTODIA!

2 Due to its high light intensity this device may not be used in close vicinity to the patient's eyes.

3 Operate and service this device exclusively in compliance with the procedures described in these instructions. The manufacturer will not be responsible for the safety of the patient if procedures other than those published are applied.

4 To prevent the risk of an electric shock, strictly use a charger approved by the manufacturer.

5 All electrical installations must comply with the applicable electrical standards and the specifications given by the manufacturer.

6 The operating and the maintenance personnel are to be trained and qualified accordingly.

7 Any repairs and modifications are only allowed to be done by qualified persons authorized by the manufacturer.

8 **DANGER - Risk of explosion!** Do not use the ASTODIA in an environment at risk of explosion or in the present of flammable anesthetics.

Safety information

1 Not to put the patients or the users at risk, please, report each of the following occurrences immediately to your local dealer.

- Damaged or worn mains cables, mains plug or socket
- Damaged housing, damaged or detached control panel
- Damaged hand piece or connecting cable

In these cases, do not use the ASTODIA before it has been repaired.

2 If the ASTODIA control unit is being charged, a safety distance of at least 1.5 m has to be kept.

3 If the red LED is applied continuously at maximum intensity to a fixed point on the surface of the skin, temperatures of between 43 and 45 °C can be reached for periods of less than one minute even when ASTODIA is being used in the intended manner.
Due to the small surface area and short amount of time, this should not be classed as a critical issue (see EN 60601-1:2006, Table 24).
The slight redness that can be seen after use is quickly reversible and does not cause tissue lesions.

4 ASTODIA may not be used for longer than 5 minutes on a fixed point on the surface of the skin.

5 Once ASTODIA has been switched on, the red and yellow LEDs each flash three times. ASTODIA may only be used after the LEDs have flashed. If the LEDs do not flash as described, ASTODIA must be serviced before being used again.

Symbols

Where these symbols are applicable, they appear at the relevant point on the device, the packaging, the rating plate or in the accompanying paperwork.

IPX0 — This symbol indicates following IEC 60529 that this device does not have specific protection against humidity.

This symbol states that this device is a Type BF applied part to standards IEC 60601-1 and VDE 0750 Part 1.

You must read the instructions for use before using this product.

Appears before the 4-digit year of manufacture.

This symbol on the control unit indicates that this device complies with the requirements of the Medical Devices Directive 93/42/ECC of 14 June 1993.

Warning.Optical radiation. Do not direct LED to the eyes.

Shift key for LED-colours - press shortly
OFF button - press and hold (ca. 1 s)

ON button
Reduce the light intensity

ON button
Increase the light intensity

International standards and classification

EN 60601-1: 1990 + A1: 1993 + A2: 1995
Electrical medical equipment, Part 1 - General safety specifications.

EN 60601-1-2: 2007
Medical electrical equipment, part 1-2: Electromagnetic compatibility-Requirements and tests.

ASTODIA complies with the requirements of the Class I (regulation 10) of the Medical Device Directive 93/42/ECC.

Liability

The manufacturer is only liable for the safety, reliability and performance of the device when all operational, maintenance and calibration procedures are carried out in accordance with the procedures published by the manufacturer and are performed by appropriately trained and qualified personnel; when, if necessary, only original spare parts are used for replacing components; when it is - assembled and repaired only be authorised personnel or an authorised service centre; when the electrical installations comply with the local applicable - regulations and the IEC-requirements and when the device is used in accordance with the operating instructions for the intended purpose and at an appropriate place.

On request, STIHLER ELECTRONIC GmbH will provide technical documentation and a spare part list.
The provision of technical documentation or spare parts does not constitute authorization from the manufacturer to open or repair the device.

Service information

ASTODIA does not include parts which can be repaired by the user. Therefore, do not try to repair the ASTODIA yourself. Contact your local dealer if required.

Warranty terms

The period of guarantee is 12 months. During the guarantee period, the manufacturer repairs or replaces the wrong parts free of charge if the malfunction is caused by defects of material or production.
Other defects are not subject to this guarantee agreement. The warranty does not cover damages caused by misuse or improper operation, applied force or damages which are caused by normal use. This applies when the device has been opened or its original state has been modified by people who are not authorized by the manufacturer.
If a case of damage occurs within the warranty period, please send the cleaned device to the next dealer or directly to STIHLER ELECTRONIC GmbH. The arising transport and packaging costs shall be paid by the sender.

Disposing of the device

Meaning of the symbol on the product, the packaging or the operating instructions: Electrical devices include valuable material and shall not be disposed of in the regular domestic waste!

Please follow the local regulations for the disposal or used products or send the cleaned and sterilized device accompanied by a corresponding explanation to STIHLER ELECTRONIC GmbH or to your next dealer. This is the way to ensure the cost-effective and professional disposal of your used appliances.

Returning a used product

The customer will be responsible for the proper packaging and identification of the returned product!

Please enclose a report which describes precisely why you have returned it, the circumstances and, if known, the cause of the return shipment.
If the device had come in contact with blood or bodily fluids, it has to be cleaned and disinfected before shipment.

To avoid transport damages, the device should be sent in its original packaging or in an other well protecting packaging.

2. Product description

Introduction

The method of transillumination or Diaphanoscopy has been used in the field of paediatrics and especially of neonatology for decades. It is used to identify a pneumothorax or a hydrocele quickly and to visualize vessels in limbs during a puncture. Until now, cold light sources with fibre-optical light cables have been used for this purpose. Nowadays, however, the light emitting diodes (LED) are more often applied. Because of its design, the ASTODIA is particularly suitable for the patient-specific application on small premature babies.

Technical Description

ASTODIA consists of a control unit, a hand piece and a charger.
Its light in the visible spectrum (yellow/red) is used for the transillumination of thin limbs (e.g. wrist joint) and for the quick identification of a pneumothorax or a hydrocele in the field of paediatrics/neonatology.
The extremely bright light of the used high-performance diodes is adjustable in 9 steps or infinitely variable. The special yellow coloured light visualizes the vessel structures particularly well, as it is required for venipuncture. The red light ensures a continuous, extensive and deep transillumination, which is required for visualizing the pneumothorax or for diagnosing the hydroceles.
The common interface on the control unit is designed for charging the integrated batteries as well as for the electrical connection of the hand piece cable.
This avoids using and charging of the device at the same time. This way, the charger, when it is charging the device, cannot be seen as a medical device in the sense of the Medical Devices Directive provided the distance to the patient (min. 1. 5 m) is kept.

Components of the ASTODIA

1	**Control unit**	It includes the complete electronic circuitry and the power supply of the unit. The interface, which is used for the charger and the hand piece ensures that the patient is only treated without galvanic connection to the power mains.
2	**Hand Piece**	Two high-performance diodes of different wave lengths (yellow and red) provide for a wide field of application. The round and edge-free design allows the transillumination also on positions which are difficult to access.
3	**Charger**	The intelligent charging management ensures that the integrated batteries work for a long time.

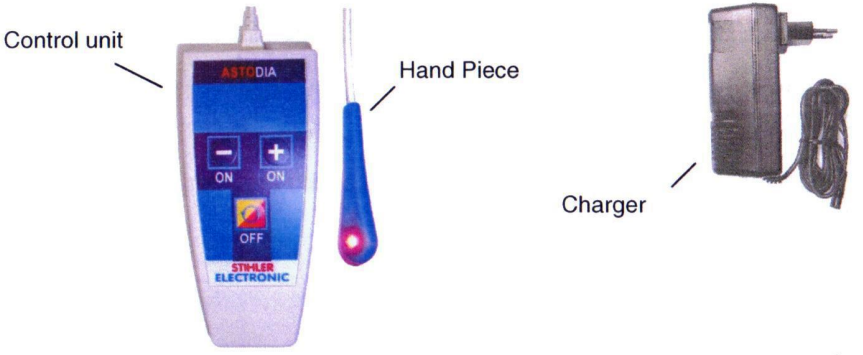

Fig. 1

Components of the control panel

1		Shift key for LED-colours - press shortly OFF button - press and hold (ca. 1 s)
2		ON button Reduce the light intensity
3		ON button Increase the light intensity

3. Commissioning and Application

1 Before you put the device into operation, charge the integrated batteries. To do this, use the belonging charger which is to plug into the interface of the control unit.

The provided charger is only allowed to be used for charging the ASTODIA.
Do not use the USB-connector for other interfaces.
The additional plugs for the secondary circuit of the charging device are not included in the package. The correct plug for ASTODIA is fixed to the charging cable. By this the correct polarity is always guaranteed.

The charging process is completed when the green indicator LED „Ready" on the charger flashes.

To apply the ASTODIA connect the hand piece with the interface of the control unit.

Fig. 2 Hand piece

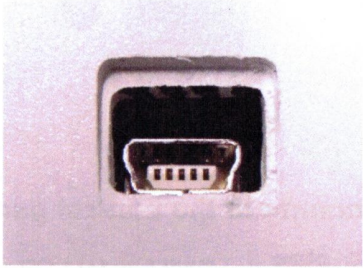

Fig. 3 Interface on the control unit

2 Before you use the device, check it for visible damages and check its function. During the functional test, make sure, that you turn the light source away from your eyes to protect your eyes.

3 Start the device directly with the keys + ON or − ON on the lowest light level.

Once ASTODIA has been switched on, the red and yellow LEDs each flash three times. ASTODIA may only be used after the LEDs have flashed. If the LEDs do not flash as described, ASTODIA must be serviced before being used again.

The device is, after of the LEDs flashed, preset to start with the red LED colour as standard.

Infinitely variable light intensity is set by pressing and holding (for at least 0.5 s) the + / − key.

If you press the button for a short time, you can change the light intensity in 8 levels.

The colour changes from RED to YELLOW and vice versa by pressing this key .

In case ASTODIA starts directly after switch on in the highest light level and a change of the highest level is not possible - then do not use ASTODIA

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4 **The transillumination effect can significantly be improved if you dim the surrounding light.**

5 If the device is constantly operated with the highest light level, it will automatically switch over to the next lower level after 2 minutes.

6 If the unit is switched on for about 5 minutes and no key is actuated during this time, it will automatically switch off to save the battery power.

7 If the battery power is low, the LED which is working at that time will start flashing. This warning can be suppressed for 5 minutes by shortly pressing any button. This can be repeated until the battery voltage reaches a critical value and the device automatically switches off.

ASTODIA may not be used for longer than 5 minutes on a fixed point on the surface of the skin.

End operation

Switch the device off by pressing and holding the key (for about 1 s).

Charging the batteries

To charge the integrated batteries only use the charger provided with the basic equipment and follow exactly the instructions of the charger.

4. Troubleshooting

Symptom	Possible cause(s)	Remedy
Device cannot be started	Battery charge too low. Hand piece is not connected. Control unit or hand piece defect.	1. Charge battery 2. Connect the hand piece. 3. Send the control unit and the hand piece to the local dealer.
Batteries cannot be charged	Charger defect. Batteries defect.	1. Replace charger 2. Return the charger and get it repaired

5. Maintenance and periodic safety checks

Preventive Maintenance

ASTODIA needs no preventive maintenance.

Cleaning and disinfecting

Clean and disinfect the control unit and the hand piece, if necessary, or when it is polluted as follows:

1. Clean all surfaces using a soft cloth/cotton swab and a mild soap solution.
2. Disinfect the control unit and the hand piece using a recommended disinfectant.
3. Only disinfect the control unit and the hand piece with a disinfectant on the basis of alcohol or with one of the recommended disinfectants.

Disinfectant	Manufacturer
Bacillol Plus	Bode Chemie
Meliseptol	B. Braun
Mikrozid Liquid	Schülke und Mayr
Mikrozid HBV pump spray	

Periodic Safety Inspection

At least every 24 months - and/or in accordance with the applicable regional and national regulations – it is necessary to check the ASTODIA Diaphanoscope for safety reasons and to document it. The check consists of the following tests:

- Visual inspection
- Check the function of the yellow and the red LED
- Check the functioning of the reduction of the maximum light intensity and the automatic switching off.
- Regionally and nationally required examinations of medical equipment (e.g. electrical safety of the ASTODIA charger)

All tests of the periodic safety inspection have to be passed!
If one of the tests does not pass, the ASTODIA has to be sent to the local dealer or to STIHLER ELECTRONIC GmbH for repair (see "Return shipment of a used product" in Chapter 1 "Introduction").

Instructions for the test

• Visual inspection

Check the following components for completeness and visible damages before each application.

- Charger
- Housing of the control unit
- Control panel
- Hand piece

• Check the function of the yellow and the red LED

- Switch on the ASTODIA on the control unit. The red and yellow LEDs each has to flash three times. The red LED must light up at its lowest level.
- Actuate the shift-key for the LED-colours. The yellow LED must light up at its lowest level.
- Check, if it is possible to change the light intensity by actuating the keys, see Chapter 3.3.
- Check, if the covering glasses of the LEDs are still clear and light-transmitting.

• Check the functioning of the reduction of the maximum light intensity and the automatic switching off.

- Switch on the ASTODIA on the control unit and set the maximum light intensity - see Chapter 3.3.
- Watch the LED and measure

  I. the time, until the ASTODIA automatically reduces the maximum light intensity by one level.
  This time must be 2 minutes +/- 10 s.

  II. the time, until the ASTODIA automatically switches off completely.
  This time must be 5 minutes +/- 30 s.

• Electrical Test

The charger has to be checked once a year according to the applicable national safety regulations.

6. Technical data

ASTODIA			
Electr. connection while charging	100 - 240 VAC ±10% 50-60Hz Charger		
Electr. connection during operation	4.8 V integrated, rechargeable battery Control unit and hand piece		
Protection class	Charger II ⧈		
IP (IEC 60529)	IPX0		
Classification as per Appendix IX	I (rule 9)		
Dimensions max. Length max. Width max. Depth	Control unit 141 mm 63 mm 33 mm	Hand piece Cable 1150 mm 19 mm 12 mm	Charger Cable 1000 mm 60 mm 50 mm
Weight	Control unit 0.2 kg	Hand piece 0.03 kg	Charger 0.4 kg
Permissible Environmental Conditions	Humidity	Temperature	Pressure
in operation in storage/ transport	10 % to 90 % 10 % to 90 % not condensing	+16 °C to +32 °C - 20 °C to +60 °C	700 hPa to 1060 hPa 500 hPa to 1060 hPa
⚠	Do not use the ASTODIA Diaphanoscope in an environment at risk of explosion.		

7. ASTODIA ordering information

Auxiliaries required for operation:

Charger
Control unit
Hand piece

1	**ASTODIA** **completely packaged consisting of:** 1 piece control unit 1 piece hand piece 1 piece charger 1 piece Operating instructions	**Order No.: DIA100**

Separate order

1	piece control unit	Order No.: DIA120
1	piece hand piece	Order No.: DIA130
1	piece charger	Order No.: DIA140
1	piece Operating instructions -English-	Order No.: 0811.7200.12

8. Package Labeling

Red Label indicating:

- Handle with care!
- Do not drop !
- Keep dry

9. Guidelines and manufacturer's declaration electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
The ASTODIA is intended for use in the electromagnetic environment specified below. The customer or user of the ASTODIA should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11/EN 55011	**Group 1**	**The ASTODIA uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.**
RF emissions CISPR 11/EN 55011	**Class B**	**The ASTODIA is suitable for use in all establishments, including domestic establishments and those directly connected to public low-voltage power supply network that supplies buildings used for domestic purpose.**
Harmonic emissions IEC/EN 61000-3-2	**Class A**	
Voltage fluctuations / flicker emissions IEC/EN 61000-3-3	**Complies**	

Guidance and manufacturer's declaration - electromagnetic immunity			
The ASTODIA is intended for use in the electromagnetic environment specified below. The customer or user of the ASTODIA should assure that it is used in such an environment.			
Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC/EN 61000-4-2	**± 6 kV contact ± 8 kV air**	**± 6 kV contact ± 8 kV air**	**Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.**
Electrical fast transient/burst IEC/EN 61000-4-4	**± 2 kV for power supply lines ± 1 kV for input /output lines**	**± 2 kV for power supply lines ± 1 kV for input /output lines**	**Mains power quality should be that of a typical commercial or hospital environment.**
Surge IEC/EN 61000-4-5	**± 1 kV differential mode ± 2 kV common mode**	**± 1 kV differential mode ± 2 kV common mode**	**Mains power quality should be that of a typical commercial or hospital environment.**
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	**< 5% U_T (> 95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (> 95% dip in U_T) for 5 sec.**	**< 5% U_T (> 95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (> 95% dip in U_T) for 5 sec.**	**Mains power quality should be that of a typical commercial or hospital environment. If the user of the ASTODIA requires continued operation during power mains interruptions, it is recommended that the ASTODIA be powered from an uninterruptible power supply or a battery.**
Power frequency (50/60 Hz) magnetic field IEC/EN 61000-4-8	**3 A/m**	**3 A/m**	**Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.**
NOTE U_T is the a.c, mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The ASTODIA is intended for use in the electromagnetic environment specified below. The customer or user of the ASTODIA should assure that it is used in such an environment.			
Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the ASTODIA, including cables, than the recommended separation distance calculated from the equation applicable to frequency of the transmitter.
Conducted RF IEC/EN 61000-4-6	**3 Vrms 150 kHz to 80 MHz**	**3 Vrms**	$d = 1,2\sqrt{P}$
Radiated RF IEC/EN 61000-4-3	**3 V/m 80 MHz to 2,5 GHz**	**3 V/m**	$d = 1,2\sqrt{P}$ **80 MHz to 800MHz**
			$d = 2,3\sqrt{P}$ **800 MHz to 2,5 GHz**
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE1. At 80 MHz and 800 MHz, the higher frequency range applies. NOTE2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ASTODIA is used exceeds the applicable RF compliance level above, the ASTODIA should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ASTODIA. [b] Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.			

Recommended separation distances between Portable and mobile RF communications equipment and the ASTODIA			
The ASTODIA is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the ASTODIA can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ASTODIA as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1,2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 1,2\sqrt{P}$
0,01	**0,12**	**0,12**	**0,23**
0,1	**0,38**	**0,38**	**0,73**
1	**1,2**	**1,2**	**2,3**
10	**3,8**	**3,8**	**7,3**
100	**12**	**12**	**23**
For transmitters rated at maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer. NOTE1. **At 80 MHz and 800 MHz, the separation distance for higher frequency range applies.** NOTE2. **These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.**			